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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/731,683

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Art Bertolero

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07/03/2008

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EXAMINER

HOPKINS, CHRISTINE D

ART UNIT

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3735

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/731,683	Applicant(s) BERTOLERO ET AL.	
	Examiner CHRISTINE D. HOPKINS	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-29, 32-64 and 66-68 is/are pending in the application.
- 4a) Of the above claim(s) 46-52 and 57-61 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-29, 32-40, 62-64, 67 and 68 is/are allowed.
- 6) ☒ Claim(s) 41-45 and 53-56 is/are rejected.
- 7) ☒ Claim(s) 66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 10 March 2008. Claims 20-29, 32-64 and 66-68 are now pending. The Examiner acknowledges the amendments to claims 20, 41 and 67, as well as the cancellation of claim 65.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 41-43, 45, 53, 54 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Fox et al. (U.S. Patent No. 5,865,730). Fox et al. (hereinafter Fox) teaches a heart stabilization device. Regarding claims 41, 42, 45, 53 and 56, Fox discloses a device comprising: a surgical tool comprising a ball **106**; a source of suction (col. 4, lines 2-3); an elongate coupling member **104** having a proximal end, a distal end, a flexible rigidifying portion **2** that can be rigidified by applying suction, and means **105** (socket) near the distal end for coupling with the surgical tool or “heart stabilizing member” or “heart positioning member” (referred to as a “foot” by Fox), and an actuation device **101** near the proximal end that can tighten the coupling means to the ball of the surgical tool and loosen the coupling means from the ball of the surgical tool, wherein the source of suction is attached with the elongate coupling member and applies a vacuum to the flexible rigidifying portion (Figs. 15 and 16).

Regarding claims 43 and 54, the heart stabilizing member comprises: at least one tissue contacting surface; at least one suction aperture for applying suction force; and at least one suction port for coupling with a source of suction (Fig. 12).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 44 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (U.S. Patent No. 5,865,730) in view of Houser et al. (U.S. Pub. No. 2003/0060685). Fox discloses the invention as claimed, see rejection supra; however Fox does not teach inflating a tissue contacting surface of the heart stabilizing or positioning member. Houser et al. (hereinafter Houser) teach a surgical instrument for contacting and stabilizing tissue of the heart. Regarding claims 44 and 55, Houser teaches a heart stabilizing or positioning member **100** having a tissue contacting surface **120**. The contacting section may be configured to provide a variety of atraumatic surfaces, as well as ways to prevent slippage and invoke immobilization of the heart. Houser teaches a member or “port” to supply vacuum, a stream of fluid, or an inflatable medium to abut the contacting section against the surface of the heart [0113]. Furthermore, Houser teaches the introduction of an inflation medium through the same conduit for supplying vacuum, which immobilizes the heart (as in the instant application). Therefore, at

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the time of the invention it would have been obvious to one having ordinary skill in the art to have provided an inflation medium as suggested by Houser to a heart stabilizing or positioning member as taught by Fox such that minimal damage is imparted to the sensitive cardiac tissue.

Allowable Subject Matter

6. Claims 20-29, 32-40, 62-64, 67 and 68 are allowable over the prior art of record. The following is a statement of reasons for the indication of allowable subject matter: regarding claims 20-29, 32-40 and 62-64, the prior art of record does not teach or fairly suggest a system for heart surgery comprising: a retractor device for access to a patient's heart through a first incision; a heart stabilizing device having a tissue contacting surface and at least one suction aperture adjacent the surface; a source of suction; and a first coupling device for coupling with the heart stabilizing device through a second incision at a separate location, the first coupling device comprising: an elongate shaft having a proximal and distal end, a flexible rigidifying portion that can be rigidified by applying suction; and a means for coupling the elongate shaft with the heart stabilizing device adjacent the distal end of the shaft, wherein the source of suction is attached with the coupling device and applies a vacuum to the flexible rigidifying portion.

Regarding claims 67 and 68, the prior art of record does not teach or fairly suggest a system for heart surgery comprising: a retract device; a source of suction; a heart stabilizing device comprising a tissue contacting surface, a suction aperture adjacent the tissue contacting surface, and a complementary coupling means; a first coupling device comprising an elongate shaft having a proximal and distal end, a flexible rigidifying portion that can be rigidified by applying suction, a distal coupling means at or near the distal end, and an actuation device at or

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near the proximal end that can tighten the distal coupling means relative to the complementary coupling means of the heart stabilizing device and loosen the distal coupling means relative to the complementary coupling means of the heart stabilizing device; and a first flexible arm coupled with the first coupling device via a first clamp, wherein the first flexible arm can be rigidified by applying suction, wherein the source of suction is attached with the coupling device and applies a vacuum to the flexible rigidifying portion.

7. Claim 66 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: regarding claim 66, the prior art of record does not teach or fairly suggest a device for heart surgery comprising: a surgical tool comprising a ball; a source of suction; and an elongate coupling member having a proximal and distal end, a flexible rigidifying portion that can be rigidified by applying suction, and a means near the distal end for coupling with the surgical tool, and an actuation device near the proximal end that can tighten the coupling means to the ball of the surgical tool and loosen it from such, wherein the source of suction is attached with the elongate coupling member and applies a vacuum to the flexible rigidifying portion, the device further comprising a flexible arm coupled to the elongate coupling member wherein the flexible arm can be rigidified by applying suction.

Response to Arguments

8. Applicant's arguments filed 10 March 2008 with respect to the rejection of claims 41-43, 45, 53-54, 56 and 65 under 35 U.S.C. 103(a) to Paolitto et al. (U.S. Pub. No. 2003/0010346)

have been fully considered but are moot in view of the new grounds of rejection under 35 U.S.C. 102(b) citing Fox et al. ('730).

9. Applicant's arguments filed 15 October 2007 with respect to the rejection of claims 44 and 55 under 35 U.S.C. 103(a) citing Paolitto et al. (U.S. Pub. No. 2003/0010346) in view of Houser et al. (U.S. Pub. No. 2003/0060685) have been fully considered but are moot in view of the new grounds of rejection presented above citing Fox et al. ('730) in view of Houser et al. (U.S. Pub. No. 2003/0060685).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./
Christine D Hopkins
Examiner
Art Unit 3735

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

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